



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

July 9, 1999

WARNING LETTER NYK 1999-53

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Tobin, Owner
Yankee Trails Inc.
Third Avenue Extension
Rensselaer, New York 12144

Dear Mr. Tobin:

On May 21, 1999, an investigator from the U.S. Food and Drug Administration (FDA) conducted an inspection of your bus company located at Third Avenue Extension. During the inspection, our investigator observed violations of the Public Health Service Act and the Food, Drug and Cosmetic Act and regulations promulgated thereunder for the Control of Communicable Diseases and Interstate Conveyance Sanitation (Title 21, Code of Federal Regulations, Parts 1240 and 1250, respectively).

At the conclusion of the inspection, the investigator presented you with a list of Inspectional Observations, form FDA 483 and discussed the findings with you. The following deviations were found:

1. There is no backflow prevention device in the water distribution system.
2. The floor is not graded to the drain.
3. There is no sign instructing employees to wash their hands before resuming work in the employee lavatory facilities.
4. There are no towels in the employee lavatory facilities.

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These violations are not intended to be an all-inclusive list of deficiencies that exist at your facility. As a result of this inspection, your facility received a "Provisional" classification. We acknowledge your correction of items 3 and 4 above. However, you should take prompt action to correct the other two violations. Failure to correct these violations may result in a reclassification of the facility to Not-Approved.

It is your responsibility to ensure your facility is in compliance with the Public Health Act and the Food, Drug and Cosmetic Act and the regulations promulgated thereunder. You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations.

Your response may be directed to Lisa M. Utz, Compliance Officer, at the above address. If you have any questions, you can reach Ms. Utz at (716) 551-4461 extension 3165.

Sincerely,


Brenda J. Holman
District Director